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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,101	08/01/2003	Marco Ciufolini	065691-0332	1920

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FOLEY AND LARDNER LLP
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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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01/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/632,101

Applicant(s)

CIUFOLINI ET AL.

Examiner

Laura L. Stockton, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007 and 20 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-60, 62-64, 66-72 and 78-97 is/are pending in the application.
- 4a) Of the above claim(s) 55-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62-64, 66-72 and 78-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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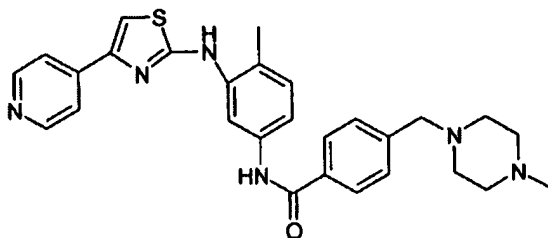
DETAILED ACTION

Claims 55-60, 62-64, 66-72 and 78-97 are pending in the application.

Election/Restrictions

Applicant's election without traverse of modified Group II, and the species of Example 80 found on pages 64-65 of the instant specification (reproduced below), in the reply filed on July 15, 2005 was acknowledged in a previous Office Action. Modified Group II embraces wherein R⁶ represents the definition of (i), (ii) and (iii).

080: 4-(4-Methyl-piperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-4-yl-thiazol-2-ylamino)-phenyl]-benzamide



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The requirement was deemed proper and made FINAL in a previous Office Action.

Subject matter not embraced by modified Group II and claims 55-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in the reply filed on July 15, 2005.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore arguments pertaining to these rejections will not be addressed.

Response to Amendment

The Declarations under 37 CFR 1.132 filed

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February 27, 2007 and September 10, 2007 are sufficient to overcome the rejection of the instant claims based upon obviousness under 35 USC 103 over Lago {WO 00/33842}, Dexter et al. {U.S. Pat. 3,467,666}, Spivack et al. {U.S. Pat. 3,201,409}, Illig et al. {U.S. Pat. 6,291,514}, Stieber et al. {U.S. Pat. 2003/0158199}, and Dhanoa et al. {U.S. Pat. 2001/0044545}, each taken alone or in combination with each other when similar utilities are asserted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-72 and 78-95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with

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the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support was found in the specification or the originally filed claims for the R⁶ variable representing broadly an aryl group substituted by NO₂ or CN in currently amended claim 67 or newly added claim 83; or for R representing an alkyl "bearing at least one nitrogen group" as found in newly added claim 94. Applicant states that support is found in Compounds 117 and 081 for the amendment to claim 67. However, a single species is seldom, if ever, sufficient to support a generic claim. In re Langer, 183 USPQ 288 (CCPA 1974). Further, the language in newly added claim 94 is not support by the instant specification on

page 8, lines 14-17. Therefore, the claims lack written description as such.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 62-64, 66-72 and 78-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 62-64, 66, 67, 83, 85, 88, 91 and 94, it is unclear what is meant by the expressions "basic nitrogen functionality" and "bearing at least one nitrogen group", which is found in several variable definitions, such as the R variable. A term is not indefinite if the determination of its meaning "is not

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beyond skill of the art and does not involve undue experimentation" In re Halleck, 164 USPQ 647. The expressions do not meet that standard because it will involve undue experimentation. Further, if there are several different ways of calculating a parameter, and the specification fails to indicate which method is to be employed, then the claims are indefinite, Harrah's Entertainment Inc. v. Station Casinos Inc., 71 USPQ2d 1439 (DC Nev 2004). In the instant case, the question is how is the basic nitrogen functionality determined? Is the "basic nitrogen functionality" or a substituent "bearing at least one nitrogen group" a Lewis base or a Brønsted base? The instant specification fails to give a clear and concise definition of the expressions "basic nitrogen functionality" and "bearing at least one nitrogen group". Is the nitrogen directly attached or indirectly attached? Additionally, the claims metes and bounds cannot be ascertained since there is no structural information, other than having a nitrogen,

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associated with the expressions "basic nitrogen functionality" or "bearing at least one nitrogen group". Therefore, the expressions "basic nitrogen functionality" and "bearing at least one nitrogen group" are indefinite.

In claim 63, it is unclear if the -COR group and the -CONRR' group are defining R" or R. See claim 64.

In claim 69, an "or" should be added before structure (f).

In claim 83, an "or" is needed after the (ii) definition of R⁶.

In claim 83, under definition (iii) of R⁷, an "or" is needed after "4-thiazolyl".

In claim 83, an "or" is needed after the (iii) definition of R⁷.

In claim 86, Examples 3, 94, etc., for instance, lack antecedent basis from claim 83.

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In claim 86, an "and" is needed before the last compound listed in the claim for proper Markush language format.

Claim 86 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period thereby establishing that no other subject matter is missing from the claim.

Claim 89 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period thereby establishing that no other subject matter is missing from the claim.

Claim 95 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period thereby establishing that no other subject matter is missing from the claim.

Claim 96 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period thereby establishing that no other subject matter is missing from the claim.

Response to Arguments

Applicant's arguments filed September 10, 2007 have been fully considered. Applicant argues that the claims have been amended thereby rendering moot the rejection under indefiniteness. In response, the instant claims have been found indefinite for the reasons stated above.

Applicant argues that: (1) the expression "a pendant basic nitrogen functionality" is not insolubly ambiguous and therefore should not be held indefinite; and (2) according to the Declaration by Marco Ciufolini (paragraphs 18-26 starting on page 12), "nitrogen functionality" can be clearly understood by a person skilled in the art.

All of Applicant's arguments and the Declaration statements have been considered but have not been found persuasive. See above statements concerning why the expression "basic nitrogen functionality" is found indefinite. Further, the instant specification fails

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to completely define the expression "basic nitrogen functionality" nor give a complete structural depiction of all the substituents, or radicals, embraced by the expression "basic nitrogen functionality". On page 17, lines 5-12 of the instant specification, examples of X substituents substituted with a "basic nitrogen functionality" is shown in structures a to f. But again, the instant specification fails to completely define the expression "basic nitrogen functionality".

The Declaration filed September 10, 2007 is by an instant common inventor. The Declaration makes the statement that "A chemist of ordinary skill in this field would readily understand what "pendant basic nitrogen functionality" refers to". The Declaration further defines "pendant" and cites patents which use the term "pendant" and/or "basic nitrogen functionality". However, none of the cited patents uses the expression "basic nitrogen functionality" in the claims to define a novel compound. It is noted

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that no text book references, for example, were submitted to define the expression "basic nitrogen functionality".

It is also noted that in the Declaration by Marco Ciufolini, a common inventor, filed February 27, 2007 (bottom of page 9 through the top of page 10), Mr. Ciufolini states "the compound is a 1,4-diamino derivative and also an amidine derivative known to be protease inhibitor, a completely different therapeutic class of kinase inhibitors. Thus, we did not expect this compound to have any activity on c-kit." This statement by Marco Ciufolini appears to raise the question that there are some nitrogen containing substituents, i.e., amidine, which should not be considered to be embraced by the language "basic nitrogen functionality". This statement by Marco Ciufolini appears to contradict Applicant's notion that one skilled in the art would readily be able to determine whether a given moiety is a "basic nitrogen

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functionality". It is very doubtful that one skilled in the art would know what the full scope that the expression "basic nitrogen functionality" embraces. Therefore, the rejection is deemed proper.

The rejection of the claims under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Application No. 10/523,018 has been overcome since Application No. 10/523,018 was abandoned after the previous Office Action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 62-64, 66-72 and 78-97 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No.

11/779,633 and over claims 31 and 32 of copending Application No. 10/567,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed compounds are generically described in 11/779,633.

Note claim 83 in instant application and claim 1 in copending Application No. 11/779,633. Note claim 31 in copending Application No. 10/567,557 as well as the

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compounds and formulas on pages 7-25 of the specification in copending Application No. 10/567,557.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., c-kit inhibitors). One skilled in the art would thus be motivated to prepare products embraced by the copending applications to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be c-kit inhibitors. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed September 10, 2007 have been fully considered. Applicant has requested that this rejection be held in abeyance until all other issues have been resolved.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains Subject matter not embraced by modified Group II and claims 55-60 drawn to an invention nonelected without traverse in the reply filed on July 15, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be

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directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

January 29, 2008